

CDC VISI Industry Forum Meeting Minutes from July 12-13, 2001

Participating Organizations

- Aventis Pasteur
- Chiron
- Glaxo Smith Kline
- Merck
- Wyeth-Lederle

Meeting Objective

- Evaluate prospective vendor presentations for the project based on the specifications and scope.
- Review of vendors, selection of potential workable candidates.
- Review of time lines and tasks for project completion.

CDC Objective

- Improve the compliance and accuracy associated with vaccine information entry. Automate the process to limit the opportunity for human error in the process of recording information.
- Provide for the capability to initiate a National database for all patients receiving vaccines.

CDC VISI Proposed Guideline

- See summary attachment based on CDC VISI draft guidelines as of April 2001 - www.cdc.gov/nip/visi/prototypes.htm.

Industry Recommendations from April 2001 Meeting.

- Adopt a three-phased approach to implement methods for improved data transfer.
 - Phase 1; Implement a single detachable label for single dose presentations that includes only the human readable required information (Generic name, Lot #, and Manufacturer). Move to multidose presentations after single dose is completed.
 - Phase 2; Form an industry working group to meet with government agencies and user groups. The group to explore the available technologies, make recommendations based on cost/benefit and appropriate technology and develop a fully automatic data transfer system.
 - Phase 3; Implement fully automatic data transfer system

Meeting Summary

- Vendors presenting at the meeting were:
 - **Electronic data transfer** - Dave Cobb, Director Business Development – Safety syringes, Inc. email: dcobb@safetysyringes.com
 - **Data Matrix and/or stacked symbologies** - Randall Kemmerer, Director Business Development – Acuity CiMatrix. Email: Rkemmerer@acut.com and Michael Montalbano, Account Manager – Saddle Brook Controls. Email: mikem@saddlebrookcontrols.com
 - **RSS symbology** - Richard P. Fox, Jr, President/CEO – Fox IV Technologies, Inc. email: foxiv@foxiv.com
 - **Detachable labels** - Peter Siedl – Schriener Labels Inc. Email: held@schreiner-etiketten.de
- Future meeting schedule for the industry sub committee was agreed to be as follows:
 - September 7, 2001 (Merck) West Point PA. Industry Sub committee meeting to review data and prepare final recommendations for the CDC-VISI general meeting.
- It was agreed to contact the FDA and request a meeting to discuss various options and compliance issues (R. Filipski)

- Based on the presentations provided, a comparison spreadsheet was prepared for the committee members.
- Each member company agreed to present the data obtained to the senior management of the respective organization for corporate agreement on the recommendations. (All members)
 - Presentation to CDC and FDA in Fall 2001.
 - Development of company specific specifications and quotations by end of Q2, 2002
 - Presentations and individual company financial approvals for the 2003 budgetary years by end of 2002.
 - Integration into production lines in 2003-2004
 - Validation and FDA approval in 2004.
 - Potential market availability in 2005.
- The committee is to provide follow-up questions for the selected vendors by July 20th for response by the vendors Sept 7th.
- Each company to provide annual number of containers and production lines by August 17th to R. Filipski for composite into an overall financial impact statement.
- Each representative to continue searching the market for any other potential vendors and/or solutions for the challenge.

Next Steps

- Provide minutes of the meeting from July 12-13, 2001. (R. Filipski)
- Forum participants to review and comment on minutes by July 20, 2001. (All Participants)
- Provide number doses, containers and operating lines for financial impact preparation. (All members by Aug. 17, 2001)
- Present data and recommendations to each respective organization. (All members by Sept 7th)
- Prepare additional vendor questions. (All by July 20th)
- Contact the FDA and CDC for dates of presentation. (R. Filipski by Sept 7th)